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EXAMINER AEDER, SEANE				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/719,534

Applicant(s)

CINCOTTA ET AL.

Examiner

SEAN E. AEDER

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Detailed Action***

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/08 has been entered.

Claims 1-19 and 21-24 are pending.

Claim 1 has been amended by Applicant.

Claims 1-19 and 21-24 are currently under consideration.

***Response to Arguments***

***Double Patenting and 35 U.S.C. 103(a) Rejection***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 1642

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6, 10, 15, 21, and 22 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 8, 13, and 19 of U.S. Patent No. 5,792,748 in view of Werning et al (Arch. Otolaryngol. Head Neck Surg., 7/95, 121:783-789), Cincotta et al (Cancer Research, 1994, 54:1249-1258), and Molitch (Endocrinol. Metab. Clin. North Am., 1992, 21(4) abstract) for the reasons stated in the Office Action of 12/27/06, the reasons stated in the Office Action of 8/28/07, and for the reasons set-forth below.

Further, claims 1-19 and 21-22 remain rejected and newly added claims 23-24 are rejected under 35 U.S.C. 103(a) as being obvious over Cincotta et al (US Patent 5,792,748; filed 6/7/95) in view of Werning et al (Arch. Otolaryngol. Head Neck Surg., 7/95, 121:783-789), Cincotta et al (Cancer Research, 1994, 54:1249-1258), and Molitch (Endocrinol. Metab. Clin. North Am., 1992, 21(4):abstract), for the reasons stated in the Office Action of 12/27/06, the reasons stated in the Office Action of 8/28/07, and for the reasons set-forth below.

The claims are drawn to methods for arresting growth or eradicating tumors in a mammal bearing one or more tumors comprising the steps of: (a) comparing the daily plasma prolactin profile of said tumor bearing mammal to a normal daily prolactin profile for healthy mammals of the same species and sex, (b) adjusting the daily plasma prolactin profile of said tumor bearing mammal by administering a prolactin enhancer at appropriate time intervals of the day such that the peak and trough of the daily circadian prolactin profile of the tumor-bearing mammal occurs at or about the same time as the peak and trough of the daily circadian prolactin profile of a healthy mammal of the same species and sex, (c) contacting cells of said tumor with a benzophenoxazine-analog photosensitizer, and (d) exposing said contacted tumor cells to light, such that the growth of said tumor is retarded or said tumor is eradicated.

Claim 3 of US Patent No. 5,792,748 is drawn to a method for inhibiting neoplastic growth in a mammal in need of such treatment comprising administering prolactin at a predetermined time during a 24-hr period. Claim 8 of US Patent No. 5,792,748 is drawn to the method of claim 3, wherein said administration adjusts the prolactin profile of said mammal to conform to or approach the standard profile of a healthy mammal of the same species and sex. Claim 13 of US Patent No. 5,792,748 is drawn to the method of claim 8 wherein the mammal is a human. Claim 19 of US Patent No. 5,792,748 is drawn to the method of claim 13, wherein said neoplasm is a member selected from the group consisting of sarcomas, fibrosarcoms, carcinomas, glioblastomas, and melanomas. Cincotta et al further teaches administering a prolactin enhancer within the peak prolactin period of said healthy mammal of the same species and sex as said

tumor bearing animal wherein said prolactin enhancer is administered between the hours of 01:00 and 04:00 (see lines 50 of column 5 to line 6 of column 6, in particular).

Werning et al teaches that combining photodynamic therapy (exposing said contacted tumor cells to light) with metoclopramide increases the percentage of tumor regression versus photodynamic therapy alone (see abstract). Metoclopramide, as evidenced by Molitch, is a prolactin enhancer.

Cincotta et al teaches that 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride is a photodynamic agent which activates solid tumors (page 1257, in particular) and that photodynamic therapy with 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride in mice resulted in direct tumor cell killing (see abstract, in particular).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to optimize the claimed invention of Cincotta et al (US Patent 5,792,748) so as to include photodynamic therapy. One would have been motivated to do so because it was previously taught in the art that combining photodynamic therapy with the administration of a prolactin enhancer resulted in the increased regression of tumors versus prolactin enhancer therapy alone. Furthermore, the teachings of Cincotta et al (Cancer Research, 1994) promote the use of highly selective photosensitizers, like 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride, for optimizing cell killing with photodynamic therapy. Thus, clearly, the combined teachings suggest to one of skill in the art a reasonable expectation of

Art Unit: 1642

success in arresting the growth of or eradicating tumors by combining photodynamic therapy with the administration of prolactin enhancers.

In the Reply of 2/27/08, Applicant argues that there is no suggestion to combine the '748 patent with Werning et al and Cincotta et al to arrive at a method of treating tumors by combining neuroendocrine resetting therapy (NRT) with photodynamic therapy (PDT). Applicant further argues that the effect observed in Werning et al is unrelated to metoclopramide's action on prolactin and Werning et al does not teach or suggest that metoclopramide is mediating effects through plasma prolactin levels. Applicant further argues that Werner fails to teach or suggest that administration of metoclopramide must occur at specific times over a 24-hour period in order to adjust the daily plasma prolactin so that the peak and trough of the daily prolactin profile of the tumor-bearing mammal occurs at or about the same time as the peak and trough of the daily prolactin profile of a healthy mammal of the same species and sex. Applicant further argues that if one of ordinary skill in the art modified a Werning teaching that metoclopramide should be administered 1 hour before and 24 and 28 hours after PDT, instead of administering metoclopramide within the peak prolactin period of said healthy mammal of the same species and sex as said tumor bearing mammal, as required by the claims, this would serve to render the Werning method inoperable for its intended use in enhancement of PDT. Applicant further cites *In re Ratti* 270 F.2d 810 (CCPA 1959); MPEP 2143.01 and states that it is well established in the law that references cannot be properly combined when combining prior art references to modify the claimed invention would render the prior art inoperable for its intended use. Applicant further

states that Werning teaches that a metoclopramide dose should be maximized to effect enhancement of PDT for tumor treatment and argues that high levels of metoclopramide would result in uniformly high prolactin levels and would not serve to reset prolactin levels. Applicant further argues that Molitch's disclosure that metoclopramide is a prolactin enhancer does not provide a suggestion to combine Cincotta with Werning to arrive at the instant claims, in view of Werning's teaching that the prolactin enhancing activity is not related to observed enhancement of PDT. Applicant further points-out that Molitch et al teaches "Pathologic increases of PRL (prolactin) owing to hypothalamic dysregulation occur with a variety of medications, including...metoclopramide" (lines 12-14 of Molitch). From said teaching, Applicant argues that Molitch does not provide evidence that metoclopramide, as administered by Werning, is a prolactin enhancer that may be used in combination with '748 patent to arrive at the instant claims. Applicant further argues that Molitch teaches explicitly that metoclopramide cannot be used to reset the daily plasma prolactin profile of a tumor bearing mammal to approach the profile of a normal mammal. Applicant further argues that unexpected synergistic results are obtained by the claimed method with the combination of neurocrine resetting therapy (NRT) and photodynamic therapy (PDT) using a prolactin enhancer, compared to either therapy alone. Applicant further states that the timing of prolactin administration is essential in order to obtain the synergistic effect of PDT and prolactin treatment and that the specification makes it clear that prolactin should be administered during the time of the plasma prolactin peak in a healthy mammal of the same sex.



The amendments to the claims and the arguments found in the Reply of 2/27/08 have been carefully considered, but are not deemed persuasive. In regards to the argument that there is no suggestion to combine the '748 patent with Werning et al and Cincotta et al to arrive at a method of treating tumors by combining neuroendocrine resetting therapy (NRT) with photodynamic therapy (PDT), it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the prolactin enhancer-based NRT of the '748 patent using the prolactin enhancer Metoclopramide taught by Molitch et al in combination with PDT of Werning et al because the '748 patent teaches prolactin enhancers are to be used in NRT (lines 50 of column 5 to line 6 of column 6, in particular), Molitch et al teaches Metoclopramide is a prolactin enhancer (see abstract, in particular), and combining two therapies (such as PDT and NRT) to treat the same disorder is obvious. In regards to the obviousness to combine PDT with NRT to treat cancer, the instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant claims, given the teachings of the prior art, it would have been obvious to combine the two cancer therapies because the idea of doing so would have logically followed from their having been individually taught in the prior art to treat cancer. One of ordinary skill in the art would have reasonably expected to obtain a

therapeutic benefit upon combining PDT and NRT since both had been demonstrated in the prior art to be reasonably predictive of treating cancer. Further, the teaching of Werning et al that combining PDT with metoclopramide treatment increases the percentage of tumor regression versus PDT alone (see abstract) indicates that metoclopramide would be a preferred prolactin enhancer to be used with the prolactin enhancer-based NRT methods of the '748 patent when combining said NRT methods with PDT methods.

In regards to the argument that the effect observed in Werning et al is unrelated to metoclopramide's action on prolactin and Werning et al does not teach or suggest that metoclopramide is mediating effects through plasma prolactin levels, a teaching of using a prolactin enhancer comes from the '748 patent and the identity of metoclopramide as a prolactin enhancer comes from Molitch et al. Further, while Werning et al does not specifically address whether metoclopramide mediates effects through plasma prolactin levels, Werning et al does not teach that metoclopramide does not have an effect on prolactin. Further, Werning et al teaches metoclopramide has multiple therapeutic benefits. Specifically, Werning et al teaches metoclopramide acts as an antiemetic agent during chemotherapy, directly damages DNA, inhibits DNA repair, enhances effects of cisplatin, and enhances effects of ionizing radiation (see pages 785 and 787, in particular). Further, it is noted that Molitch et al teaches "the precise role and mechanism of metoclopramide as an effective adjunct to PDT is not clearly defined. However, metoclopramide clearly enhances the efficacy of PDT against xenografted HSCC and likely will enhance the effects of PDT in other tumor model

Art Unit: 1642

systems as well". Therefore, with all the therapeutic benefits of metoclopramide, including enhancement of PDT, metoclopramide would be an obvious prolactin enhancer to use when combining the prolactin enhancer-based NRT methods of the '748 patent with PDT methods.

In regards to the argument that Werner fails to teach or suggest that administration of metoclopramide must occur at specific times over a 24-hour period in order to adjust the daily plasma prolactin so that the peak and trough of the daily prolactin profile of the tumor-bearing mammal occurs at or about the same time as the peak and trough of the daily prolactin profile of a healthy mammal of the same species and sex, when to administer prolactin enhancers in the prolactin enhancer-based NRT methods of the combined teaches is taught by the '748 patent (see lines 50 of column 5 to line 6 of column 6, in particular).

In regards to the argument that if one of ordinary skill in the art modified a Werning teaching that metoclopramide should be administered 1 hour before and 24 and 28 hours after PDT, instead of administering metoclopramide within the peak prolactin period of said health mammal of the same species and sex as said tumor bearing mammal, as required by the claims, this would serve to render the Werning method inoperable for its intended use in enhancement of PDT, one of skill in the art would not have performed the combined teachings in such a manner because when to administer prolactin enhancers in the prolactin enhancer-based NRT methods of the combined teaches is taught by the '748 patent (see lines 50 of column 5 to line 6 of column 6, in particular).

In regards to the argument that it is well established in the law that references cannot be properly combined when combining prior art references to modify the claimed invention would render the prior art inoperable for its intended use, when and how to administer the prolactin enhancer of the combined methods (metoclopramide) is taught by the '748 patent (see lines 50 of column 5 to line 6 of column 6, in particular). One of skill in the art would expect such a combination, intended to treat and eradicate tumors, would operably treat and eradicate tumors.

In regards to the argument that Werning teaches that a metoclopramide dose should be maximized to effect enhancement of PDT for tumor treatment and that high levels of metoclopramide would result in uniformly high prolactin levels and would not serve to reset prolactin levels, Werning teaches that metoclopramide provides therapeutic benefits at all doses tested (see Figures 1 and 2, in particular) and the '748 patent provides clear guidance as to how one is to determine the dose of a prolactin enhancer that would reset prolactin levels in prolactin enhancer-based NRT methods (columns 8-9, in particular).

In regards to the citation "Pathologic increases of PRL (prolactin) owing to hypothalamic dysregulation occur with a variety of medications, including...metoclopramide" (lines 12-14 of Molitch) and the argument that Molitch et al does not provide evidence that metoclopramide, as administered by Werning, is a prolactin enhancer that may be used in combination with the '748 patent to arrive at the instant claims, Molitch et al teaches metoclopramide is a prolactin enhancer (see abstract) and the '748 teaches a method that is to use prolactin enhancers (see lines 50

of column 5 to line 6 of column 6, in particular). While Molitch et al does not provide a working example of the methods of the combined teachings, as cited above, the methods of the combined teachings are obvious for the reasons stated above.

In regards to the argument that Molitch teaches explicitly that metoclopramide cannot be used to reset the daily plasma prolactin profile of a tumor bearing mammal to approach the profile of a normal mammal, no such teaching is found in Molitch et al.

In regards to the argument that unexpected synergistic results are obtained by the claimed method with the combination of NRT and PDT using a prolactin enhancer, compared to either therapy alone, methods of combining PDT with metoclopramide (a prolactin enhancer) are anticipated by a *single reference*. Further, Werning teaches, *in a single reference*, the result that combining PDT with metoclopramide (inherently a prolactin enhancer capable of NRT) results in 100% tumor regression without re-growth. While Werning et al does not teach that metoclopramide treatment results in NRT, the prior art has already demonstrated, in a single reference, that combining PDT with metoclopramide (a prolactin enhancer) results in 100% tumor regression without re-growth. Thus, Applicant's arguments have not been found persuasive and the rejections are maintained.

### ***Double Patenting Rejection***

Claims 1-4, 10, 15, and 21 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 13, 28, and 30 of U.S. Patent No. 6,071,914 in view of Lin (Cancer Cells, 1991, 3(11)) and Cincotta

et al (Cancer Research, 1994, 54:1249-1258) for the reasons stated in the Office Action of 12/27/06, the reasons stated in the Office Action of 8/28/07, and for the reasons set forth below.

The Office Action of 12/27/06 contains the following text:

"Claim 1 of U.S. Patent 6,071,914 is drawn to a method for treating a patient suffering from a neoplasm comprising the steps of: comparing the blood prolactin level of said patient at each of a plurality of spaced apart time points during a 24-hour period to the corresponding prolactin level of a baseline prolactin level of healthy humans of the same sex as said patient; and adjusting the prolactin level of said patient to cause the patient's prolactin profile approach or conform to the baseline prolactin profile by administering a prolactin reducer to said mammal at a predetermined time, thereby inhibiting growth of said neoplasm in said human. Claim 12 of U.S. Patent 6,071,914 is drawn to the method of claim 1, further comprising administering a prolactin enhancer to said patient. Claim 13 of U.S. Patent 6,071,914 is drawn to the method of claim 12, wherein said prolactin reducer is bromocriptine and said prolactin enhancer is melatonin. Claim 18 of U.S. Patent 6,071,914 is drawn to a method for treating a patient suffering from a neoplasm comprising adjusting the prolactin level of said patient to cause the patient's prolactin profile to approach or conform to the baseline prolactin profile by administering a prolactin reducer to said patient at a predetermined time, thereby inhibiting the growth of said neoplasm in said human. Claim 28 of U.S. Patent 6,071,914 is drawn to the method of claim 18, wherein said method further comprises administering a prolactin enhancer to said patient. Claim 30 of U.S. Patent 6,071,914 is

drawn to the method of claim 28, wherein said prolactin reducer is bromocriptine and said prolactin enhancer is melatonin.

Lin summarizes the state of the art of photodynamic therapy of malignant tumors, including the use of selective photosensitizers like phthalocyanine dyes and iodinated benzophenothiazine (pages 439-439, in particular).

Cincotta et al (Cancer Research) also teaches that photodynamic therapy is a promising new approach for the selective eradication of neoplastic tissue and further teaches the successful use of 5-ethylamino-9-diethylamino-benzo[a]phenothiazinium chloride. A benzophenoxazine analog, as a photosensitizing agent and teaches a method of treating tumors in a mammal with said photosensitizing agent and that photodynamic therapy of EMT-6 tumors in mice with said photosensitizing agent resulted in direct tumor cell killing.

In the absence of unexpected results, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine photodynamic therapy with the patented invention of adjusting prolactin levels since each of these methods had been taught by the prior art to successfully eradicate neoplasm. Clearly, the instant situation is amenable to the type of analysis set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Thus, one of ordinary skill in the art

would have reasonably expected to successfully treat tumors using both methods combined."

In the Reply of 2/27/08, Applicant states: "For the reasons identical to those set forth above in Section IV the claims are not obvious over the combination of the teachings of the '914 patent and Cincotta, because unexpected results are obtained with the combination of NRT and PDT, compared to either therapy alone".

The arguments found in the Reply of 2/27/08 have been carefully considered, but are not deemed persuasive. These arguments have been addressed above. Further, the arguments addressed above do not address a single reference cited in this rejection. Thus, Applicant's arguments have not been found persuasive and the rejection is maintained.

### ***Summary***

Summary

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1642

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SEA

/Sean E Aeder/

Examiner, Art Unit 1642